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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 30-34 are presented for examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed January 19, 2010 was received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1-11 and 30-34 remain pending and under examination. Claims 1 and 7 are amended.

Applicant's arguments, filed January 19, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135) and Bren ("Losing Weight: Start by Counting Calories", *FDA Consumer Magazine*, 2002 Jan-Feb; Pub. No. FDA 04-1303C, p.1-6), each already of record, for the reasons of record set forth at p.6-12 of the previous Office Action dated October 15, 2009, of which said reasons are herein incorporated by reference.

Newly amended claim 1 remains properly included in the present rejection because the addition of the limitation "and the long-chain n-3 polyunsaturated fatty acid is administered to said mammal for the purpose of decreasing the appetite of said mammal" is a reiteration of the preamble objective of the claimed method (i.e., for decreasing the appetite of an obese or overweight mammal) and, thus, fails to impart any additional distinguishing feature to the claim that was not already present in previously pending claim 1. As a result, the claim remains rejected for the reasons already of record, which will not be repeated herein so as not to burden the record, but are herein incorporated by reference.

Furthermore, though the reason to combine the cited teachings may not be identical to Applicant's reason (i.e., to decrease the appetite of the treated mammal), the fact that Applicant has recognized another therapeutic advantage (i.e., the claimed decrease in appetite) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., to reduce elevated levels of C-reactive protein, which is a marker of inflammation, in patients exhibiting increased levels of C-reactive protein). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose this effect on appetite is immaterial because the

combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention and, in addition, products of identical composition cannot have mutually exclusive properties such that whatever effect(s) this same combination of elements has on decreasing appetite must necessarily be present in the combination of teachings of the cited prior art, absent factual evidence to the contrary. Applicant is reminded that the claiming of a new use, new function or unknown property that is necessarily present in the prior art does not necessarily make the claim patentable. Moreover, per the guidance provided in *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594), the burden is now shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 593, second column, first full paragraph), which Applicant has not done.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the cited references fail to provide any apparent reason to combine or modify the references to arrive at the claimed limitation directed to enteral administration at the time prior to or in conjunction with an appetite-impacting stimulus for the purpose of decreasing the appetite of the mammal and treat obesity or conditions of overweight. Applicant alleges that the "appetite-impacting stimulus" is defined in the instant specification as a stressor or stimulus that has the effect of increasing food intake and gives examples of irregular meals, sleep deprivation, and parental expectations to excel in school and/or sports, and *is not* the "general condition which is present in an individual at all times, as suggested by the Office". (p.12, Remarks) Applicant again insists that there is no mention anywhere in the cited references that the formulation of Phinney et al. will affect the appetite of obese or overweight mammals whose appetite needs to be decreased. Still further, Applicant alleges that claim 1 requires the appetite of the mammal to be one that needs to be decreased and states that the Office is in agreement that not all obese or overweight mammals have an appetite that needs to be

decreased. Still further, Applicant alleges that the Office takes the position that overweight or obese mammals in need of a decrease in appetite is a subgenus of the larger genus of obese or overweight mammals, more particularly mammals exhibiting elevated levels of C-reactive protein, but insists that there is no disclosure of the claimed invention in the cited references and, therefore, the instantly claimed invention is not obvious. Applicant repeatedly opines that the combination of references fails to teach and/or suggest and/or recognize that administering the formulation of Phinney et al. will affect the appetite of obese or overweight mammals whose appetite needs to be decreased.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's argument that the cited references fail to teach enteral administration at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal is unpersuasive for the following reasons: (1) Phinney et al. explicitly teaches the administration of DHA-containing formulation orally (i.e., "enterally" as in instant claim 1 and 33), such as via capsules, tablets, pills, soft gel-caps, powders, solutions, dispersions or liquids (p.23, l.34-36), (2) Phinney et al. also explicitly teaches the administration of DHA in an exemplary amount of 10-10,000 mg (p.27, l.23-31), which meets Applicant's defined amount of instant claim 6 as an amount of the active long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal and (3) the administration as disclosed by Phinney et al. meets the limitation directed to administration "at a time prior to or in conjunction with an appetite-impacting stimulus" because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood such that growth of the human body in any of these three stages (i.e., infancy, adolescence or adulthood) would necessarily be present at any time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth and, therefore, in view of the fact that Applicant has only provided an exemplary list of stimuli that constitute

the "appetite-impacting stimulus" as instantly claimed, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary. Accordingly, Applicant's allegation that the reference to Phinney et al. fails to meet these limitations of the instant claims is clearly without merit.

Applicant continues to stress that the conditions of administration as disclosed in Phinney et al. do not meet the requirement of administering "prior to or in conjunction with an appetite-impacting stimulus". This is, and will remain, unpersuasive because Applicant has provided only an *exemplary definition of what constitutes such appetite-impacting stimuli as instantly claimed*. Thus, while a period of growth as described *supra* may not fall within those exemplary stressors that Applicant has listed in the instant specification as constituting an "appetite-impacting stimulus", the stimulus as instantly claimed is not limited to the specific conditions described in the specification and Applicant has failed to provide any evidence that the interpretation provided by the Office (i.e., that the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood such that growth of the human body in any of these three stages would necessarily be present at any time the composition was administered and would be reasonably considered a period of stress on the human body that requires increased food intake and proper nutrition and health in order to permit such growth and, thus, is an "appetite-impacting stimulus") is unreasonable and excluded by the instant claims. In the absence of such evidence to support Applicant's allegations, it is maintained that this interpretation is reasonable and consistent with the art and, therefore, the conditions of administration as disclosed by Phinney et al. meet Applicant's claimed limitation directed to administration "prior to or in conjunction with an appetite-impacting stimulus", absent factual evidence to the contrary. Note that the use of an exemplary definition (such as that used by Applicant in the instant case) does not explicitly define what is and what is not within the scope of the term. As a result, Applicant's emphatic insistence that the Office's

interpretation is not within the scope of the term is clearly an unimpressive argument because there is no clear delimiting explanation as to what is included or excluded by this claim limitation.

Secondly, Applicant continues to insist that the cited references do not teach or suggest that the formulation of Phinney et al., when administered, will affect the appetite of obese or overweight mammals whose appetite needs to be decreased. This is again, as before, unpersuasive. Though it is acknowledged that Phinney et al. does not explicitly teach the reduction in appetite in an obese or overweight mammal or the identification of an overweight or obese mammal, Phinney et al. provides a clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, e.g., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual evidence demonstrating that a subpopulation of such patients suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the intent to reduce C-reactive protein and with the reasonable expectation of the same (or at least substantially equivalent) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Moreover, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be

necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

Thirdly, Applicant alleges that claim 1 requires the appetite of the mammal to be one that needs to be decreased and states that the Office is in agreement that not all obese or overweight mammals have an appetite that needs to be decreased. This is also unpersuasive. The newly cited reference to Bren teaches that, to combat obesity in overweight or obese patients, one should maintain a healthy diet and weight and to make smart choices about their diet (p.1, para.4-5), including reduced calorie consumption via cutting back on the number of calories eaten by eating smaller amounts of food and choosing foods lower in calories (p.4, para.1-3). Thus, the teaching of an obese human patient as in Visser et al. is also clearly a mammal who needs a decrease or reduction in appetite to maintain a healthy and/or normal weight, as evidenced by Bren, and, therefore, meets the requirement of Applicant's instantly claimed mammal in need of a decreased appetite. Moreover, while it may very well be agreed that not *all* obese or overweight mammals have an appetite that needs to be decreased (e.g., such as a patient with a genetic abnormality that causes the obesity and not due simply to overeating), Bren still provides the factual evidence that, of all obese and/or overweight patients, there is clearly a subpopulation therein that *is in need of* a reduction in appetite to control the obese and/or overweight condition.

Fourthly, Applicant alleges that the Office takes the position that overweight or obese mammal in need of a decrease in appetite is a subgenus of the larger genus of obese or overweight mammals, more particularly mammals exhibiting elevated levels of C-reactive protein, but insists that there is no disclosure of the claimed invention in the cited references and, therefore, the instantly claimed invention is not obvious. This is unpersuasive because, as evidenced by the myriad of reasons given *supra*, the instantly claimed invention is obvious in light of the cited prior art and Bren clearly provides the factual evidence that, of this population of obese and/or overweight patients to be treated as suggested by the prior art of Phinney et al. in view of Visser et al., there is clearly a subpopulation therein that is clearly in

need of a reduction in appetite to control the obese and/or overweight condition, which clearly meets Applicant's instantly claimed subject to be treated.

Fifthly, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, as combined, clearly dictate to the contrary.

Sixthly, and lastly, though the reason to combine the cited teachings may not be identical to Applicant's reason (i.e., to decrease the appetite of the treated mammal), the fact that Applicant has recognized another therapeutic advantage (i.e., the claimed decrease in appetite) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., to reduce elevated levels of C-reactive protein, which is a marker of inflammation, in patients exhibiting increased levels of C-reactive protein). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose this effect on appetite is immaterial because the combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention and, in addition, products of identical composition cannot have mutually exclusive properties such that whatever effect(s) this same combination of elements has on decreasing appetite must necessarily be present in the combination of teachings of the cited prior art, absent factual evidence to the contrary. Applicant is reminded that the claiming of a new use, new

function or unknown property that is necessarily present in the prior art does not necessarily make the claim patentable. Moreover, per the guidance provided in *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594), the burden is now shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 593, second column, first full paragraph), which Applicant has not done.

For these reasons *supra*, and those previously made of record at p.6-12 of the Office Action dated October 15, 2009, rejection of claims 1-4, 6 and 30-33 is proper.

Claims 7-9, 11 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135) and Bogentoft (WO 87/03198; 1987), and further in view of The Merck Index (Monograph 792, p.121) and Bren ("Losing Weight: Start by Counting Calories", *FDA Consumer Magazine*, 2002 Jan-Feb; Pub. No. FDA 04-1303C, p.1-6), each already of record, for the reasons of record set forth at p.12-17 of the previous Office Action dated October 15, 2009, of which said reasons are herein incorporated by reference.

Newly amended claim 7 remains properly included in the present rejection because the addition of the limitation "and the long-chain n-3 polyunsaturated fatty acid and the long-chain n-6 polyunsaturated fatty acid are administered to said mammal for the purpose of decreasing the appetite of said mammal" is a reiteration of the preamble objective of the claimed method (i.e., for decreasing the appetite of an obese or overweight mammal) and, thus, fails to impart any additional distinguishing feature to the claim that was not already present in previously pending claim 7. As a result, the claim remains rejected for the reasons already of record, which will not be repeated herein so as not to burden the record, but are herein incorporated by reference.

Furthermore, though the reason to combine the cited teachings may not be identical to Applicant's reason (i.e., to decrease the appetite of the treated mammal), the fact that Applicant has recognized another therapeutic advantage (i.e., the claimed decrease in appetite) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise have been obvious and the combination would have been made for another valid reason (i.e., to reduce elevated levels of C-reactive protein, which is a marker of inflammation, in patients exhibiting increased levels of C-reactive protein). Please see *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fact that the prior art does not disclose this effect on appetite is immaterial because the combination of such elements would have naturally commended itself to one of ordinary skill in the art at the time of the invention and, in addition, products of identical composition cannot have mutually exclusive properties such that whatever effect(s) this same combination of elements has on decreasing appetite must necessarily be present in the combination of teachings of the cited prior art, absent factual evidence to the contrary. Applicant is reminded that the claiming of a new use, new function or unknown property that is necessarily present in the prior art does not necessarily make the claim patentable. Moreover, per the guidance provided in *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594), the burden is now shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 593, second column, first full paragraph), which Applicant has not done.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that again that neither Phinney et al. nor Visser et al., alone or in combination, teaches or suggests each and every limitation of the claimed invention and lacks any apparent reason to combine their teachings. Applicant further asserts that Bogentoft and Merck fail to overcome these shortcomings because each reference fails to teach or suggest administering a

composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus. Still further, Applicant alleges that Bogentoft teaches away from the instant invention because the disclosure at p.2 suggests that ingestion other than the delivery of fat directly to the ileum would not result in the food intake reduction that is seen with the method of Bogentoft, which is not needed if the instant invention is used. Applicant alleges that the Office has misinterpreted the arguments against Bogentoft, stating that it is not Applicant's position that Bogentoft does not teach enteric preparations, but rather that the Bogentoft allegedly teaches that methods of fat ingestion other than the delivery of fat directly to the ileum (i.e., the mechanism by which the invention of Bogentoft delivers fat) does not result in a reduction in food intake. Applicant submits also that it would not have been obvious to combine the formulation of Phinney et al., which is used to treat symptoms of inflammatory conditions by reducing elevated levels of C-reactive protein, with Bogentoft, which uses fatty acids in an enteric preparation for treating obesity to reduce weight. Applicant again urges that Bogentoft only discloses and enables fatty acids having up to 18 carbon atoms and, thus, fails to disclose administering an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms and alleges the Examiner has relied upon hindsight to combine the cited references.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, with regard to Applicant's continued assertions that neither Phinney et al. nor Visser et al., alone or in combination, teach or suggest each and every limitation of the claimed invention and that the rejection lacks any apparent reason to combine their teachings, Applicant is directed to p.12-17 of the Office Action dated May 23, 2008 as to why there is an apparent reason to combine the disclosures of Phinney et al. and Visser et al. and further why such a combination of references teaches and suggest each and every limitation of the claimed invention but for the concomitant use of a long-chain n-6 polyunsaturated fatty acid (which is remedied by the citations to Bogentoft and Merck). In the interest of

brevity in the record, Applicant is directed thereto for such an explanation, which will not be repeated herein so as not to burden the record.

Secondly, Applicant's assertion that the cited references to Bogentoft and Merck fail to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, *as combined*, clearly dictate to the contrary.

Thirdly, Applicant states it is his position that Bogentoft allegedly teaches that methods of fat ingestion other than the delivery of fat directly to the ileum (i.e., the mechanism by which the invention of Bogentoft delivers fat) do not result in a reduction in food intake and, thus, teach away from the claimed invention. This is also unpersuasive. The paragraph upon which Applicant relies to support his position specifically states that "ileal infusion of a fat emulsion in connection with a meal brings about that a smaller amount of food is ingested than what should otherwise be the case". There is no indication in this paragraph that Bogentoft purports that his ileal infusion reduces the amount of food ingested as compared to *any other known method of reducing food intake*. This is an unsupported generalization of what is actually taught by Bogentoft that has no clear foundation in the reference disclosure. In actuality, Bogentoft teaches that the disclosed ileal infusion reduces the amount of food ingested "*than what should*

otherwise be the case", i.e., if the ileal infusion was not administered. This is clearly supported by the teachings of Bogentoft at p.6-7, wherein Bogentoft summarizes the results of subjects who ate until they felt full and were either control subjects (i.e., no infusion administered) or test subjects that received either an infusion of the disclosed formulation, and clearly demonstrates that the subjects administered the infusion exhibited markedly reduced food intake. Accordingly, Applicant's attempts to establish that Bogentoft somehow teaches away from the claimed invention are not, for the reasons *supra*, persuasive in establishing this alleged position.

Fourthly, Applicant's allegation that there is no reason to employ the composition of Bogentoft for use with the composition of Phinney et al., which is directed for use in treating symptoms of inflammatory conditions by reducing elevated levels of C-reactive protein in patients with such elevated levels, is unpersuasive. As previously explained *supra*, the use of the tocopherol-DHA composition of Phinney et al. for the purpose of reducing C-reactive protein in conditions characterized by elevated C-reactive protein in a obese patient population that is known in the art (as evidenced by Visser et al.) to exhibit elevated C-reactive protein is clearly taught and suggested by the cited references to Phinney et al. in view of Visser et al. The concomitant use of the composition of Bogentoft would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention because the composition of Bogentoft is effective for treating obesity and, therefore, such a person would have been motivated to combine the two therapies to (1) reduce levels of C-reactive protein that are known to be elevated in patients with obesity and (2) treat the condition of obesity (i.e., with the composition of Bogentoft) to thereby reduce the precipitating cause of elevated C-reactive protein in such obese patients. Accordingly, in view of such reasons, Applicant's allegation that there is no reason to combine the composition of Bogentoft with that of Phinney et al. is clearly without merit.

Fifthly, Applicant's assertion that Bogentoft is not properly cited prior art because the reference only discloses and enables fatty acids having up to 18 carbon atoms and, therefore, fails to disclose the

administration of an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms is unpersuasive because Bogentoft was not cited for a teaching of long-chain n-3 polyunsaturated fatty acids. This element of the claimed invention is very clearly addressed by the cited reference to Phinney et al. Rather, Bogentoft was cited for its teaching of a composition that comprises fatty acids and animal fats in the form of a triglyceride, of which arachidonic acid (i.e., the long-chain n-6 polyunsaturated fatty acid instantly claimed; see, e.g., instant claim 8) is the major constituent of animal fats. Therefore, the length of the long-chain n-3 polyunsaturated fatty acids in Bogentoft is irrelevant to the fact that the reference clearly teaches a fatty acid composition, of which it is shown that arachidonic acid is a major component (as evidenced by Merck), and, thus, clearly would have been *prima facie* obvious to one of ordinary skill in the art to combine with the composition of Phinney et al. for the reasons described *supra*.

Sixthly, and lastly, Applicant's argument that the Examiner's rationale is grounded in hindsight analysis is clearly unpersuasive. Applicant is reminded that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. However, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Considering the fact that the present rejection under 35 U.S.C. 103(a) relies solely on the knowledge and motivation that was generally available to one of ordinary skill in the art at the time of the invention (as clearly elucidated *supra*, as well as in each of the previous Office Actions) and does not improperly rely upon Applicant's disclosure, the assertion that the present rejection is made with impermissible hindsight reconstruction is unpersuasive.

For these reasons *supra*, and those previously made of record at p.12-17 of the Office Action dated October 15, 2009, rejection of claims 7-9 and 11 and 34 is proper.

Conclusion

Rejection of claims 1-11 and 30-34 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Leslie A. Royds/
Primary Examiner, Art Unit 1614

September 11, 2010